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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,232	02/18/2004	Preston W. Estep III	Longenity 001	9464

7590 08/15/2006

Preston W. Estep III
11 Willard Rd.
Weston, MA 02493

EXAMINER

MILLER, MARINA I

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 08/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/780,232

Applicant(s)

ESTEP, PRESTON W.

Examiner

Marina Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-54 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-20 and 47-54 drawn to a method of generating a responsive cellular profile, classified in class 702, subclass 19.
- II. Claims 21-27, drawn to a method of determining the presence, intensity, stage, or level of a biological state of a subject, classified in class 702, subclass 19.
- III. Claims 28-29 and 41-45, drawn to a method of determining the presence, intensity, stage, or level of physiological states of a subject, classified in class 702, subclass 19.
- IV. Claims 30-44 and 46, drawn to a method of determining a level of effect of therapies upon a subject, classified in class 702, subclass 19.

The inventions are distinct, each from the other because of the following reasons:

The method of Inventions I-IV can be shown to be distinct because they are physically and functionally different and are not required one for the other. In the instant case of distinct inventions, each method has a different goal and method steps. For example, Invention I is directed to a method of generating a responsive cellular profile. Invention II is directed to a method of determining a biological state of a subject. Invention III is directed to a method of determining physiological states of a subject. Invention IV is directed to a method of determining a level of effect of therapies upon a subject. Additionally, the methods of Inventions I-IV each comprise steps requiring manipulations of data that are not required for any other Invention.

Because these Inventions are distinct for the reasons given above and the non-patent and patent literature search required for each group is not coextensive with that requirement for another group, restriction for examination purposes as indicated is proper.

Species Election

This application contains claims directed to the following patentably distinct species:

Species A: elect one type of cellular profile from: transcription, translation, and protein activity recited, for example, in claims 4 and 42.

Species B: elect one cell population among those recited, for example, in claim 5.

Species C: elect one biological sample among those recited, for example, in claim 6.

Species D: elect one biological state among those recited, for example, in claims 9-15 and 23-24.

i) if applicants elect a state of dietary or nutritional health, applicants are further required to elect one state of dietary health among those recited in claim 10;

ii) if applicants elect a non-disease state, applicants are further required to elect one non-disease state among those recited in claim 12;

iii) if applicants elect a pre-disease state and early disease state, applicants are required to further elect a state from those recited in claim 14.

Species E: elect one parameter among the presence, intensity, stage, and level of a state of a subject recite, for example, in claims 21-22 and 28.

Species F: elect one therapy among those recited, for example, in claims 17 and 34-35.

i) if applicants elect food ingredients recited in claim 35, then applicants are further required to elect one substance recited in claim 36.

Species G: elect one bioactive agent among those recited in claim 49.

Species H: elect one calibration agent among those recite, for example, in claims 52 and 54.

i) if applicants elect a cell as a calibration agent recited in claim 54, applicants are further required elect one cell type recited in claim 54.

The species are independent or distinct because:

Spices of group A, different cellular profiles, are distinct because they are independent, have different structure, and data generated for one cellular profile is expected to be different from the data generated for any other cellular profile.

Species of group B, different cells, are distinct because they are structurally and functionally different and are not required one for the other. Data generated for one cell type is expected to be different from the data generated for any other cell type.

Species of group C, different biological samples, are distinct because they are structurally and functionally distinct and independent. Data generated for one sample is expected to be different from the data generated for any other sample.

Species of group D, different biological states, are distinct because they are independent and data generated for one biological state is expected to be different from the data generated for any other biological state.

Species of group E, different parameters assessing a state of an individual, are distinct because they are not required one for the other and data generated for one parameter is expected to be different from the data generated for any other parameter.

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Species of group F, different therapies, are distinct because they are not required one for the other and data generated for one therapy is expected to be different from the data generated for any other therapy.

Species of group G, bioactive agents, are distinct because they have different structure and function, are not required one for the other, and are generally disclosed in different literature.

Species of group H, different calibration agents, are distinct because they have different structure and function, are not required one for the other, and are generally disclosed in different literature.

Applicant is required under 35 U.S.C. 121 to elect ONE species from EACH Species A-D and respective sub-species enumerated above for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Currently, claims 1-3, 7-8, 16, 18-20, 30-33, 37-41, 45-48, 50-51, and 53 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Miller whose telephone number is (571)272-6101. The examiner can normally be reached on 8-6, M-Thu.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, Ph. D. can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marina Miller
Examiner
Art Unit 1631

MARJORIE A. MORAN
PRIMARY EXAMINER

Marjorie A. Moran
8/7/06

MM